Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19T1.21
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Reproductive & Respiratory Forms, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prime Pac PRRS RR - Merck Animal Health Prime Pac PRRS RR - No distributor specified
Date of Compilation Summary	February 07, 2019

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Reproductive and Respiratory Syndrome Virus</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease caused by PRRS virus (PRRSv)</td></tr>
<tr><td>Product Administration</td><td>single dose</td></tr>
<tr><td>Study Animals</td><td>16 litters of 8 pigs each, divided into 4 vaccinates and 4 controls (128 total pigs), 22-23 days of age, negative for anti-PRRSv antibodies and PCV2 viremia at 2 independent study sites.</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged with PRRSv, 4.5 weeks after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs were evaluated 14 days post-challenge.</td></tr>
<tr><td>Results</td><td>Lung lesion score (LLS) reflects the approximate volume percentage of the lung that is affected by PRRS-associated pneumonia, and is expressed as %.

<table>
<tr><td colspan="6">5-number summary of the LLS across all litters</td></tr>
<tr><td></td><td>Minimum</td><td>Q 1</td><td>Median</td><td>Q 3</td><td>Maximum</td></tr>
<tr><td>Site 1--Vaccinate</td><td>0</td><td>4</td><td>8</td><td>15</td><td>37</td></tr>
<tr><td>Site 1-Placebo</td><td>6</td><td>20</td><td>30</td><td>38</td><td>75</td></tr>
<tr><td>Site 2--Vaccinate</td><td>0</td><td>2</td><td>7</td><td>14</td><td>38</td></tr>
<tr><td>Site 2--Placebo</td><td>7</td><td>27</td><td>31</td><td>39</td><td>60</td></tr>
</table>

Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>April 25, 2017</td></tr>
</table>

Table 1: Lung Scores across all litters

Site 1:	LLS (%)	
	Vaccinate	Placebo
	0	6
	0	7
	1	7
	1	10
	3	10
	3	15
	3	17
	4	20
	4	20
	4	21
	5	25
	6	27
	7	27
	7	28
	8	29
	8	29
	8	30
	8	31
	9	32
	10	32
	10	34
	11	35
	12	37
	15	38
	15	39
	17	40
	18	41
	20	46
	21	53
	24	58
	25	60
	37	75

Site 2:	LLS (%)	
	Vaccinate	Placebo
	0	7
	0	17
	0	22
	1	22
	1	23
	2	25
	2	25
	2	25
	2	27
	3	28
	4	28
	4	29
	5	29
	5	30
	5	31
	7	31
	7	31
	7	32
	7	33
	8	34
	8	34
	10	37
	13	37
	13	38
	15	40
	15	43
	15	43
	16	47
	16	48
	18	48
	23	49
	38	60

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Reproductive and Respiratory Syndrome (PRRS)</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against reproductive disease caused by PRRS virus (PRRSv)</td></tr>
<tr><td>Product Administration</td><td>1 dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>20 vaccinates, 20 control 6-month-old gilts, negative for anti-PRRSv antibodies and PCV2 viremia. Pigs were bred 55-60 days following vaccination and confirmed bred.</td></tr>
<tr><td>Challenge Description</td><td>Pigs were challenged with PRRSv, at 83-85 days of gestation, 20 weeks post vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>For all challenged pigs, farrow metrics were recorded and offspring were observed until 21 days post farrow.</td></tr>
<tr><td>Results</td><td>Data Summary

<table>
<tr><th></th><th>Number of Gilts</th><th>Total Pigs Born</th><th>Pigs Born Live</th><th>Pigs Born Viable</th><th>Pigs Weaned</th></tr>
<tr><td>Vaccinate</td><td>20</td><td>262</td><td>209</td><td>175</td><td>149</td></tr>
<tr><td>Control</td><td>20</td><td>237</td><td>47</td><td>21</td><td>5</td></tr>
</table>

Raw data shown on attached page.</td></tr>
<tr><td>USDA pproval Date</td><td>July 7, 2017</td></tr>
</table>

Table 1: Farrow metrics – ordered by number of pigs weaned

Group	Animal ID	Litter Size	Live Born Viable	Born Dead	Non-Viable Live Born	Pre-Wean Mortality	Pigs Weaned
Vaccinate	128	15	14	0	1	2	12
Vaccinate	133	16	12	3	1	0	12
Vaccinate	142	13	12	1	0	0	12
Vaccinate	113	15	11	1	3	0	11
Vaccinate	126	16	12	1	3	1	11
Vaccinate	146	14	13	1	0	2	11
Vaccinate	124	16	13	0	3	3	10
Vaccinate	122	13	9	3	1	0	9
Vaccinate	136	12	12	0	0	3	9
Vaccinate	106	12	10	0	2	2	8
Vaccinate	116	15	12	1	2	5	7
Vaccinate	120	15	9	3	3	2	7
Vaccinate	145	14	7	1	6	0	7
Vaccinate	121	10	8	2	0	2	6
Vaccinate	132	15	7	5	3	1	6
Vaccinate	180	8	7	1	0	1	6
Vaccinate	129	14	5	4	5	1	4
Vaccinate	105	14	2	11	1	1	1
Vaccinate	156	15	0	15	0	0	0
Vaccinate	101[1]	13	na	na	na	na	na
Placebo	123	15	3	7	5	0	3
Placebo	151	13	2	8	3	1	1
Placebo	153	14	3	9	2	2	1
Placebo	104	18	0	16	2	0	0
Placebo	112	12	1	11	0	1	0
Placebo	119	17	0	16	1	0	0
Placebo	125	8	0	8	0	0	0
Placebo	134	14	1	9	4	1	0
Placebo	141	15	0	15	0	0	0
Placebo	143	18	4	14	0	4	0
Placebo	152	15	0	15	0	0	0
Placebo	154	14	4	4	6	4	0
Placebo	165	14	0	14	0	0	0
Placebo	166	15	0	14	1	0	0
Placebo	167	11	0	11	0	0	0
Placebo	170	13	0	13	0	0	0
Placebo	174	11	3	6	2	3	0
Placebo	108[2]	8	na	na	na	na	na
Placebo	168[2]	13	na	na	na	na	na
Placebo	177[2]	7	na	na	na	na	na

1 : Animal died at 11 days post challenge of congestive heart and lung failure
2 : Animal failed to farrow
na : Not applicable

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>1 mL dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>677 pigs, 3 weeks of age (17-24 days) at 3 study sites</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for one hour after vaccination and then daily for 14 days</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Frequency of adverse events (total 677 pigs)</th><th>Number</th></tr>
<tr><td>Injection Site Swelling</td><td>0</td></tr>
<tr><td>Lethargy</td><td>29</td></tr>
<tr><td>Poor feed conversion</td><td>8</td></tr>
<tr><td>Conjunctivitis</td><td>6</td></tr>
<tr><td>Loss of condition</td><td>6</td></tr>
<tr><td>Tachypnea</td><td>6</td></tr>
<tr><td>Arthritis</td><td>4</td></tr>
<tr><td>Cough</td><td>4</td></tr>
<tr><td>Death*</td><td>4</td></tr>
<tr><td>Dehydration</td><td>4</td></tr>
<tr><td>Lameness</td><td>4</td></tr>
<tr><td>Anorexia (a)</td><td>3</td></tr>
<tr><td>Diarrhea</td><td>3</td></tr>
<tr><td>Rhinitis</td><td>3</td></tr>
<tr><td>Trauma NOS (b)</td><td>2</td></tr>
<tr><td>Dermatitis and eczema</td><td>1</td></tr>
<tr><td>Respiratory tract disorder NOS</td><td>1</td></tr>
<tr><td>Weight loss</td><td>1</td></tr>
<tr><td>No adverse events</td><td>639</td></tr>
</table>
*Affirmed by licensee to have a cause other than vaccination.
</td></tr>
<tr><td>USDA Approval Date</td><td>December 23, 2016</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>1 dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>664 gilts, 173-185 days of age at 3 geographically distinct study sites.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for one hour after vaccination and then daily for 14 days.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Frequency of adverse events (total 664 pigs)</th><th>Number</th></tr>
<tr><td>Injection Site Reaction NOS[1]</td><td>1</td></tr>
<tr><td>Lameness</td><td>6</td></tr>
<tr><td>Death</td><td>2</td></tr>
<tr><td>Behavioral Disorder NOS[2]</td><td>2</td></tr>
<tr><td>No adverse events</td><td>653</td></tr>
</table>
[1]Not Otherwise Specified. The localized swelling was approximately 1 cm and was present from 7 through 12 days after vaccination.
[2]Pen-jumping (1 pig); subject of aggression from pen-mates (1-pig)

Lameness, Death, and Behavioral adverse events were affirmed by the licensee to a have cause other than vaccination.
</td></tr>
<tr><td>USDA Approval Date</td><td>January 3, 2018</td></tr>
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